MEDIREG® II, MEDISELECT® II

MEDICAL HIGH PRESSURE REGULATORS

GB

FR

DE

NL

INSTRUCTION FOR USE

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1. Foreword

GCE Medical Regulators are medical devices classified as class IIb according to the Medical Device Directive 93/42/EEC.
Their Compliance with essential requirements of 93/42/EEC Medical Device Directive is based upon EN 10524-1 standard.

2. Intended use

GCE Medical Regulators are designed for use with high-pressure medical gas cylinders equipped with a medical cylinder valve. They regulate pressure and flow of medical gases to the patient. They are intended for the administration of the following medical gases in the treatment, management, diagnostic evaluation and care of the patient:

- oxygen;
- nitrous oxide;
- air for breathing;
- helium;
- carbon dioxide;
- xenon;
- specified mixtures of the gases listed.
- air or nitrogen to power surgical tools.

3. Operational, transport and storage safety requirements

	Operations	Transport	Storage
Keep the product and its associated equipments away from			
- heat sources (fire, cigarettes, …),	✓	✓	✓
- flammable materials,	✓	✓	✓
- oil or grease, (especially be carefull if hand cream is used)	✓	✓	✓
- water,	✓	✓	✓
- dust.	✓	✓	✓
The product and its associated equipments must be prevented from falling over.	✓	✓	✓
Always maintain oxygen cleanliness standards.	✓	✓	✓
Use only the product and its associated equipments in well ventilated area.	✓		

Before initial use the product should be kept in its original packaging. GCE recommends use of the original packaging (including internal sealing bag and caps) if the product is withdraw from operation (for transport, storage).

Statutory laws, rules and regulations for medical gases, accident prevention and environmental protection must be observed.

Operation conditions

-20/+60 ℃

10/100 %

600/1200 mbar

Storage and transport conditions

-30/+60 ℃

10/100 %

600/1200 mbar

- **In case of storage at a temperature below -20 ℃, d o not operate the regulator until it has been allowed to increase its temperature to a minimum of -20 ℃**

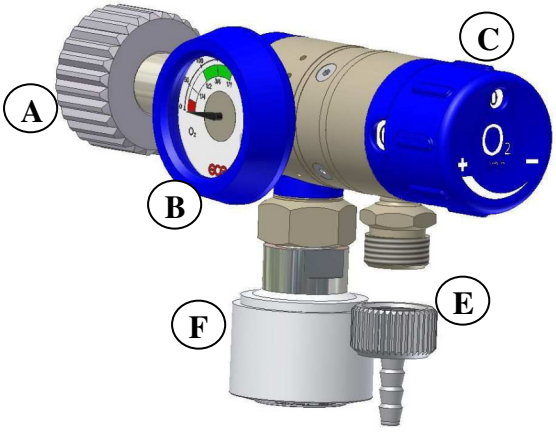
- **At regulators intended for use with mixture of medical gases O_2+N_2O is lower operation temperature limit +5℃. During normal use the flow outlet and pressure outlet will sometimes have a frosty appearance. This is a normal physical reaction in the valve, due to that the gas is going from high pressure to low pressure (Joule Thompson effect). Ensure that all equipment that is connected to the valve by at least a 2 metre hose.**

4. Personnel instructions and training

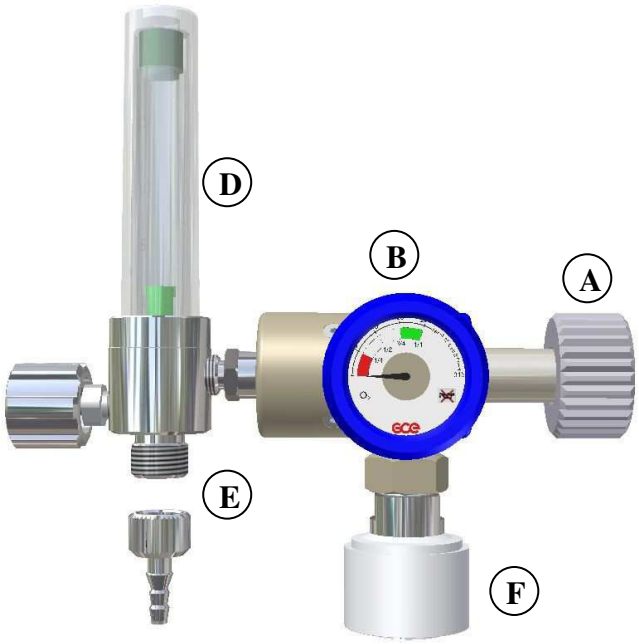
According to Medical Devices Directive 93/42/EEC the product owner must ensure that all personnel handling the product are provided with the operating instructions & performance data and are fully trained to carry out that operation. Trainees need to be supervised by an experienced person.

5. Product description

The regulator acts as a pressure-reducer, gas from the cylinder valve passes through the pressure regulator to the user outlets.



(Typical configuration of MediSelect II regulator)



(Configuration of MediReg II regulator with flowmeter)

A - Inlet stem

Regulator is fitted to the medical cylinder valve by mean of an inlet stem. The stem can be bull nose type (male thread), nut type (female thread) or pin index type. The inlet stem includes a filter.

B - Pressure gauge

A cylinder contents pressure gauge is provided to indicate the cylinder contents (the medical cylinder valve shut-off valve must be set to the ON position to allow the pressure to register on the gauge).

C, D, E – Flow-metering device and flow outlet

GCE regulators can be supplied with a flow-metering device - flow control head “C” or flowmeter “D”. This function is used to supply a gas flow (l/min) at atmospheric pressure directly to the patient through the flow outlet “E”, e.g. through a cannula or a facemask.
The flow outlet “E” can be hose nipple (for cannula or mask) or outlet with thread (for humidifier).

F - Pressure outlet

The regulator may be fitted with a pressure outlet. The pressure outlet is the outlet directly from the low-pressure chamber. Two types of the pressure outlet can be used:

Pressure outlet I - is fitted with a gas specific medical quick connector also called “quick coupler” . The user can connect another piece of equipment to this outlet with a gas specific male probe. The quick connector self seals when the male probe is disconnected. This outlet is for supplying gas at a controlled pressure to power medical devices, e.g. medical ventilator.

Pressure outlet II – is fitted with a threaded connector. The regulator with this type of pressure outlet shall be only an integral part of a medical equipment (e.g. emergency ventilators, anaesthesia devices, etc.)

⚠ • **If the regulator is fitted with two pressure outlets, do not use both of them at the same time. If you use both of them in the same time the performance of the regulator will not be according to specification (see appendix 1) !!!**

Note also that the product colour (especially flow control knob) might not be gas specific colour coded.

6. Operations

6.1 Before use

Visual Inspection before use

- Check if there is visible external damage to the product (including product labels and marking) and on the gas cylinder. If it shows signs of external damages, remove it from service and identify its status.

- Visually check if the product or the medical gas cylinder is contaminated; if needed, for the regulator, use the cleaning procedure detailed in this section (if required for the cylinder, refer to the gas cylinder manufacturer cleaning recommendation).
- Check if the product service is due or that the total life time of the product and the gas cylinder has not been exceeded, (refer to GCE or owner's date coding system). If service or life time has been exceeded, remove the product (or the gas cylinder) from service & suitably identify its status.
- Ensure that the product inlet stem is compatible with the medical cylinder valve (gas/ thread type).
- Check the presence & the integrity of inlet stem seals / correct size of seal.

⚠ • **Remove caps from inlet and/or flow outlet. Keep caps in a safe place for reuse during transport or storage.**

⚠ • **The product is dedicated only for use with the gas specified on its labelling. Never try to use for another gas.**

Fitting to medical cylinder valve

- Secure the gas cylinder stand.

Screw connection (bull nose or nut type)

- Manually screw the bull nose or the nut onto the cylinder valve connector.
- Turn the regulator into the correct position for use and tighten the nut by hand - do not use tools.

Pin index connection

- Position the pin-index over the cylinder valve with the pin(s) on the pressure regulator pointing towards the cylinder valve connector holes on the cylinder valve.
- Press the regulator inlet connection pins into the cylinder valve connector holes - do not use force, otherwise the pins or holes may be damaged.
- Tighten the screw on the regulator onto the cylinder valve connector via the T-bar handle. Do not use tools.

- Position the equipment so that the regulator user outlets point away from personnel or patient.

⚠ • **Fitting the regulator with too high a torque to the cylinder valve may result in damage.**

⚠ • **During fitting to the cylinder valve, do not apply torque/load to any other parts of the product.**

Leakage check before use

- For regulators fitted with a flow-metering device, set the flow control knob on the "ZERO" position - Ensure the flow control knob engages correctly.
- Open the cylinder valve slowly by turning the hand wheel in anticlockwise direction approx 1 to 1½ turns.

⚠ • **Sudden opening of the cylinder valve could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the cylinder valve could reduce actual flow delivered.**

- Visually check possible leakages:

- regulator inlet connection to cylinder valve
- pressure gauge to main body
- pressure relief valve vent hole(s)
- flowmeter (if any)

- Turn off the cylinder valve by turning the hand wheel in an clockwise direction to stop position. Do not use excessive force.

⚠ • **If any leakage is detected, use the procedure in chapter 6.3 and return the product to GCE for service.**

Functional checks before use

- Ensure the flow control knob is on the “ZERO” position.
- Ensure the cylinder valve is open – in the “ON” position.
- Check that the gauge indicates pressure/contents. If the pointer reaches the red area send the cylinder for the filling
- For regulators fitted with a flowmetering device check that there is gas flow at each setting (for instance, by listening for the sound of gas flow or checking presence of bubbles in a humidifier).
- Turn off the shut off cylinder valve by turning the hand wheel in a clockwise direction to the stop position. Do not use excessive force.
- Reset the flow control knob to on the “ZERO” position once the gas flow stops and the regulator is vented..
- For regulators fitted with a pressure outlet, ensure it is functional by connecting and disconnecting a male QC probe.

6.2 User outlet(s) connection & use

List of recognised accessories

To be connected to the flow outlet:
Humidifiers, breathing masks or cannulas, gas savers, nebulizers.

To be connected to the pressure outlet:
Flexible hoses, flow meters, Venturi suction ejectors.

⚠ • **At regulators fitted with pressure outlet together with ejector outlet don´t use quick coupler and ejector outlet in the same time. Especially when inlet pressure is bellow 50 bar it may negatively affect performance of the regulator.**

⚠ • **Before connecting any accessory or medical device to the regulator, always check that it is fully compatible with the product connection features & the product performances.**

Pressure outlet connection

Pressure outlet I

- Ensure the male quick coupler is compatible with the pressure outlet feature.
- Connect the male quick coupler.
- Check if the male quick coupler is fully engaged.

⚠ • **Regulator with threaded connector as pressure outlet shall be only an integral part of medical equipment. Do not use it for other purposes!**

Pressure outlet II

- Ensure the counterpart is compatible with the pressure outlet features.
- Screw the counterpart.
- Check the counterpart is fully screwed.

- **When is pressure outlet used by medical product with high flow consumption (for example lung ventilator with request of source flow 100 l/min at minimal pressure 2,8 bar) check the required capacity of source device with regulator pressure outlet performance listed in appendix 1. To obtain enough performance of the regulator is recomended replace cylinder when gauge reach the red area.**

Flow outlet connection

- **When connecting any accessory to the flow outlet make sure that it is not connected to the patient before operating the product.**

- Ensure the hose/humidifier is compatible with the flow outlet feature.
- Push the hose onto the regulator flow outlet/outlet for humidifier.
- Ensure the hose/humidifier is well engaged.

Use of product through the flow outlet (Flow setting)

- Ensure that the flow control knob is on the ZERO position.
- Ensure that the accessory is connected to the flow outlet.
- Slowly open the cylinder valve by turning the hand wheel in anticlockwise direction approx 1 to 1½ turns.

- **Sudden opening of the cylinder valve could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the cylinder valve could reduce actual flow delivered.**

- Set the flow control knob on the required one of the available flow rates.

- **Always ensure that the flow control knob has engaged and not placed between two settings otherwise the flow selector will not deliver the correct flow of medical gas.**

- **Do not try to apply an excessive torque on the flow control knob when it stops on the maximum flow position or in zero position.**

- **The oxygen flow rate must be prescribed and administered by a clinically trained user.**

After completion of the therapy

- Turn off the cylinder valve by turning the hand wheel in a clockwise direction to stop position. Do not use excessive force.
- Vent gas pressure from downstream equipment.
- Reset flow control knob on the ZERO position when gas venting has ceased.
- Disconnect the tube/humidifier from the flow outlet.

Use of product through the pressure outlet

- Ensure that the flow control knob is on the ZERO position (if any).
- Ensure the accessory IS NOT connected to the pressure outlet.
- Slowly open the cylinder valve by turning the hand wheel in anticlockwise direction approx 1 to 1½ turns.

⚠ • **Sudden opening of the cylinder valve could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the cylinder valve could reduce actual flow delivered.**

- Connect the accessory to the pressure outlet.

After completion of the therapy
- Turn off the cylinder valve by turning the hand wheel in a clockwise direction to the stop position. Do not use excessive force.
- Vent gas pressure from downstream equipment.
- Disconnect the male QC probe from the pressure outlet.

6.3 After use

- Turn off the cylinder valve by turning the hand wheel in a clockwise direction to the stop position. Do not use excessive force.
- Reset the flow control knob on the “ZERO” position – when the gas venting has ceased (valid for version with flow-metering device only).
- Ensure the pressure gauge does not show any residual pressure.
- Remove connections from user outlets.
- Refit pressure outlet and flow outlet protection caps. Before refitting the caps, ensure they are clean.

7. Cleaning

Remove general contamination with a soft cloth damped in oil free oxygen compatible soapy water & rinse with clean water.
Disinfection can be carried out with an alcohol-based solution (spray or wipes).
If other cleaning solutions are used, check that they are not abrasive and that they are compatible the product materials (including labels) and gas.

⚠ • **Do not use cleaning solutions containing ammonia!**

⚠ • **Do not immerse in water or any liquid.**

⚠ • **Do not expose to high temperature (such as autoclave).**

8. Maintenance

8.1 Service and Product Life time

Serial number and date of production

Form of nine digit serial number stamped on the product is following:
YY MM XXXXX
YY: year of production
MM: month of production

XXXXX : sequence number

Example: serial number 090300521 shows the regulator produced in March 2009, with sequence number 521.

Service

GCE recommend that a product *Periodic inspection* is undertaken every year to check proper functionality of the regulator.
GCE recommend that after 5 years of operation an *Overall maintenance* function is undertaken. This maintenance consists of preventive maintenance operations, replacement of critical components and re-testing of the product. *Overall maintenance* shall be carried out by GCE authorised person only.
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It should not be assumed that the Periodic Inspection and Overall Maintenance period recommended by GCE cover every safety procedure or practice required by local regulations or statutory requirements, or that abnormal or unusual circumstances may not warrant or suggest further requirements or additional procedures.

Life time

Maximum life time of the product is 10 years.
At the end of the product's life time, the product must be withdrawn from service. The owner shall put in place a relevant procedure to ensure the product cannot be used again.

8.2 Repairs

Repairs

Repairs activities cover the replacement of the following damaged or missing components:

- Inlet stem,
- Flow-metering device,
- Gauge,
- Piston,
- Pressure relief valve,
- Quick coupler.

The repairs shall be carried out by a GCE authorised person only.

Any product sent back to a GCE authorised person for maintenance shall be properly packaged. The purpose of the maintenance has to be clearly specified (repair, overall maintenance). For product to be repaired a short description of fault and any reference to a claim number might be helpful.

Some repair activities concerning to the replacement of the damaged or missing components can be carried out by the owner of the product. The following parts can be replaced only:

- Caps,
- Flow knob and stickers,
- Hose nipple (including o-ring),
- Inlet stem o-ring.

- **Contact our customer service for appropriate component number**

- **All labels on the equipment must be kept in good, legible condition by the owner and the user during the entire product life time.**

- **All seals and o-rings must be kept in dry, dark and clean environment by the owner and the user during the entire product life time.**

- **Use only original GCE components!**

9. Glossary

	Consult instruction for use		Suitable for Home care use
	Caution		Suitable for Hospital care use
	Keep away from heat and flammable material		Suitable for Emergency care use
	Keep away from oil and grease	SN	Serial number
	Upper and lower humidity limit	REF	Reference number
	Upper and lower temperature limit	LOT	Batch number
	Keep dry		Fragile
	Date of manufacture		Manufacturer
	Use by date		Weight of product
	Inlet parameter		Outlet parameter
P_1	Inlet pressure range	P_2	Outlet pressure
P_4	Max outlet pressure (closing pressure)	Q	Outlet flow
	Service or disposal date The serial number indicates the year the product has to undergo the overall maintenance activities or has to be disposed off. Refer to the serial number note to determine the Overall maintenance or disposal.		Ambient pressure limit

10. Warranty

GCE guarantees the regulator for one year or in accordance with statutory warranty rights, from date of delivery, against faulty design, material & workmanship.
GCE shall not be liable for loss of production, loss of profit or any other consequential damage or indirect loss. In the event of any fault in the goods due to defective design, materials or workmanship, our liability is limited to replacement of these goods, provided that written notification is given to GCE within three months of the date of delivery or

deemed delivery, or such shorter time as may be specified in the quotation. Goods returned to GCE will not be accepted unless GCE written consent to their return has previously been obtained.
The liability of the regulator is irrevocably transferred to the owner or operator to the extent that it is modified, serviced or repaired by personnel not employed or authorised by GCE or if the apparatus is used in a manner not conforming to its intended use.
GCE cannot be held responsible for the misuse of the equipment in case of non-application of the instructions for use.

APPENDIX :
Nr 1- Technical and performance data
Nr 2 - Quick coupling feature and connecting/disconnecting procedure

Manufactured by
GCE s.r.o.
Zizkova 381
583 81 Chotebor
Czech Republic

Tel : +420 569 661 111
Fax : +420 569 661 602
http://www.gcegroup.com

CE 0434